SECTION 7.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter Information

AUG 0 8 2009

Submitter's Name:	Davol Inc.
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Contact Person:	Gail Dow
Date of Preparation:	June 3, 2009

B. Device Name

Trade Name:	Bard® 3DMAX™ Light Mesh
Common/Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh, Polymeric

C. Predicate Device Name

Trade name:	Bard® Soft Mesh (Davol Inc.)
Trade name:	Bard® 3DMAX™ Mesh (Davol Inc.)
Trade name:	Mersilene Mesh (Ethicon, Inc.)

D. Device Description

The Proposed Bard® 3DMAX™ Light Mesh, is designed to fit the inguinal anatomy. The device is anatomically shaped and preformed with sealed edges that allow for easier positioning of the device than a traditional flat sheet of mesh in a laparoscopic inguinal hernia repair. The device is constructed of knitted polypropylene monofilaments 0.0048 inches in diameter. The knit construction allows the mesh to be stretched in both directions in order to accommodate and reinforce tissue defects. The device contains an orientation marker in an "M" shape to designate the medial edge of the mesh and an arrow pointing to the medial aspect. Both the arrow and "M" will aid the user during positioning and placement of the device. The orientation marker is composed of polypropylene monofilament dyed with Phthalocyaninato(2-) copper colorant.

E. Intended Use

The Bard® 3DMAX™ Light Mesh is a sterile, single use device indicated for use in the reinforcement of soft tissue where weakness exists, such as the repair of hernia defects.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

Bard® 3DMAX™ Light Mesh, the currently marketed Bard® 3DMAX™ Mesh, Bard® Soft Mesh and Ethicon Mersilene Mesh devices are all indicated for repair of hernia defects. The intended use for the 3DMAX™ Light Mesh is the same as the Predicate devices, Soft Mesh and 3DMAX™ Mesh, with the exception of the removal of the indication for repair of chest wall defects.

The Predicate Bard® Soft Mesh is a major component of the Proposed 3DMAX™ Light Mesh and both are made from the same polypropylene monofilaments with a diameter of approximately 0.0048 inches. The Proposed 3DMAX™ Light Mesh has similar physical attributes and performance characteristics as the Predicates 3DMAX™ Mesh, Soft Mesh, and Mersilene Mesh. Furthermore, it has similar materials and manufacturing methods as the Predicate 3DMAX™ Mesh.

The key differences in the Proposed 3DMAX™ Light Mesh compared to the currently marketed 3DMAX™ Mesh are the diameter of the polypropylene monofilament and the knit pattern of the mesh. In order to create a thin lightweight mesh and reduce the amount of material used in the mesh compared to traditional monofilament polypropylene meshes, the Proposed 3DMAX™ Light Mesh is constructed from monofilaments with a diameter of approximately 0.0048 inches. However, the weights (grams/square inch) of Mersilene Mesh (0.0274) and Soft Mesh (0.0282) are comparable to the 3DMAX™ Light Mesh (0.0272). In addition, the Proposed 3DMAX™ Light Mesh has larger pore knit construction than the Predicate Bard 3D Max™ Mesh.

The 3DMAX™ Light Mesh, and the Predicate 3DMAX™ Mesh are similar as both are designed to fit the inguinal anatomy. Unlike the Predicates, Mersilene Mesh and Soft Mesh, which are flat mesh sheets, the Proposed 3DMAX™ Light Mesh is anatomically shaped and preformed with sealed edges that allow for easier positioning in a laparoscopic inguinal hernia repair. The edge seal design will be the same as the currently marketed 3DMAX™ Mesh, however a layer of polypropylene mesh will be added during the edge seal lamination process to provide sufficient material to create a smooth, non-porous edge.

Unlike the Predicates, Mersilene Mesh and Soft Mesh, the Proposed 3DMAX™ Light Mesh and the currently marketed 3DMAX™ Mesh contain a medial marker composed of polypropylene monofilament and Phthalocyaninato(2-) copper colorant.

G. Performance Data

Laboratory bench testing was performed to assess the effects of the new characteristics of the Proposed 3DMAX™ Light Mesh. These tests compared the Proposed Product against the Predicate Products Soft Mesh, 3DMAX™ Mesh and Mersilene Mesh. In accordance with FDA's "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" (March 2, 1999), tests included physical and performance evaluations of the products in terms of thickness, pore size, density, stiffness, tensile strength, percent elongation, suture pullout strength, burst strength and tear resistance. Laboratory testing discussed in this submission demonstrates that the material chosen and the design utilized in manufacturing 3DMAX™ Light Mesh is substantially equivalent to the referenced Predicate Products. The results of this testing are in Section 15.

Additionally, biocompatibility testing covering the polypropylene material used in the Proposed 3DMAX™ Light Mesh, as well as the orientation marker composed of polypropylene monofilament and Phthalocyaninato(2-) copper colorant have received acceptable results. Results are summarized in Section 14.0 and copies of the test reports are in Exhibit 4.

The results show that the 3DMAX™ Light Mesh is substantially equivalent to the currently marketed Predicate devices. Therefore, based on laboratory testing and biocompatibility data, the Proposed 3DMAX™ Light Mesh, is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 3 2009

C.R. Bard, Inc.
% Ms. Gail Dow
Regulatory Affairs Associate
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K091659
Trade/Device Name: Bard® 3DMax™ Light Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: June 3, 2009
Received: June 9, 2009

Dear Ms. Dow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): Not Known

Device Name: **Bard® 3DMAX™ Light Mesh**

Indications for Use: The Bard® 3DMAX™ Light Mesh will be indicated for use in the reinforcement of soft tissue where weakness exists, such as the repair of hernia defects.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091659